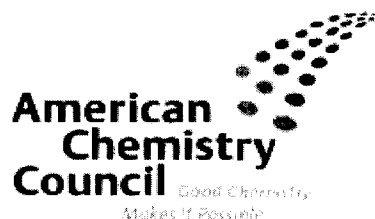


COURTNEY M. PRICE
VICE PRESIDENT
CHEMSTAR



January 29, 2004

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Via US Mail and e-mail: sabella@niehs.nih.gov

Ms. Anna Lee Sabella
Report on Carcinogens Group
National Institute of Environmental Health Science
P.O. Box 12233 MD EC-14
79 T.W. Alexander Drive, Room 3123
Research Triangle Park, NC 27709

Re: National Toxicology Program's Public Meeting to Discuss the Review Process and the Listing/Delisting Criteria Used for the Report on Carcinogens
Comments of the Naphthalene Panel

Dear Ms. Sabella:

The Naphthalene Panel (Panel) of the American Chemistry Council (ACC) appreciates this opportunity to comment on the review process used by the National Toxicology Program (NTP) in the Report on Carcinogen (RoC) program. NTP is to be commended for soliciting comments on means to improve the RoC process.

Although NTP has made some incremental changes to the RoC in recent years and has recently proposed some additional incremental changes, NTP should recognize that additional improvements are necessary to increase the scientific quality of the documentation of decisions and to clearly demonstrate NTP's response to public and stakeholder comments. The Panel has been frustrated by the absence of substantive opportunities for public input in the recent process of considering naphthalene for listing in the 11th RoC. In the Panel's experience, neither NTP's background document nor public comments seem to be considered by any of the three committees that review RoC nominations, and none of the scientific comments submitted by the Panel or other stakeholders in response to several *Federal Register* solicitations have yet to be addressed in any public forum. Based on this experience, the Panel fully supports ACC's suggestion that sweeping changes be made to the RoC process to increase transparency and science-based methodology as well as to include meaningful opportunities for scientific interchange, public comment and stakeholder involvement in the decision-making process. The Panel also fully supports ACC's suggestion that the criteria for listing/delisting substances in the RoC be clarified.

NEITHER NTP'S BACKGROUND DOCUMENT NOR PUBLIC COMMENTS SEEM TO BE CONSIDERED BY ANY OF THE THREE COMMITTEES THAT REVIEW RoC NOMINATIONS

In response to *Federal Register* notices,¹ the Panel has submitted comments regarding naphthalene on the proposed nomination (comments dated September 24, 2001), the *Draft Background Document* (comments dated October 2, 2002), and the "Working Group for the Report on Carcinogens – RG-2 Naphthalene Review" review (comments dated November 4, 2002). The Panel also made an oral presentation in the brief seven minutes allowed at the Board of Scientific Counselors (BSC) RoC Subcommittee (Subcommittee) meeting on November 19, 2002. Most recently, the Panel again submitted comments on the nomination of naphthalene to be listed in the 11th RoC (comments dated March 24, 2003).

As part of the RoC process, NTP has elicited recommendations on the listing of naphthalene from NTP Staff (the "RG-1" working group), from NTP's Executive Committee (the "RG-2" working group) and from the BSC RoC Subcommittee. Unfortunately, the RG-1 review occurred before publication of the *Draft Background Document*, the RG-2 review occurred after publication of the background document but before the date for receipt of public comments, and the BSC RoC Subcommittee based its decision apparently in large measure on information newly introduced at the Subcommittee meeting and not made publicly available as of this date by NTP either on its website, in a revised background document, or in minutes of the meeting. Indeed, as of this date the *Draft Background Document* has yet to be revised and there has been no response to any comments submitted by any member of the public in any public forum.

The process NTP followed for the nomination, review, and proposed listing seems to have included little effort to engage public stakeholders in the process, and little effort to ensure that "[NTP's] three scientific review committees are basing their decisions on the same basic material augmented by the additional public comments obtained during the review process."² Indeed, members of the public who were not physically present at the Subcommittee meeting have no reason to even be aware that a substantial part of the apparent basis for the Subcommittee's recommendation is not part of the public record. This information was not shared prior to the Subcommittee meeting with either Subcommittee members or the public, and has only been made publicly available because the Panel attached the official transcript of the meeting to its comments dated March 24, 2003, which were subsequently posted on NTP's web site.

¹ 66 Fed. Reg. 38430 (July 24, 2001); 67 Fed. Reg. 14957 (Mar. 28, 2002); 67 Fed. Reg. 36621 (May 24, 2002); 67 Fed. Reg. 59301 (Sep. 20, 2002); 68 Fed. Reg. 3033 (Jan. 22, 2003).

² Letter from Dr. K. Olden, Director of NTP, to Ms. C. Price, Vice-President, CHEMSTAR of the American Chemistry Council dated March 11, 2003.

NONE OF THE SCIENTIFIC COMMENTS SUBMITTED BY THE PANEL OR OTHER STAKEHOLDERS IN RESPONSE TO SEVERAL FEDERAL REGISTER SOLICITATIONS HAVE YET TO BE ADDRESSED IN ANY PUBLIC FORUM AND THE PUBLIC HAS BEEN DENIED THE OPPORTUNITY TO REVIEW OR COMMENT ON MATERIALS CRUCIAL TO ONE REVIEW COMMITTEE'S DECISION.

In the current RoC process, it seems as though the meeting of the BSC RoC Subcommittee is envisioned by NTP as the principle opportunity for public engagement in discussions of the scientific basis for RoC listing/delisting decisions. The fact that there is insufficient time for even Subcommittee members to review and adequately discuss the scientific basis of RoC listing decisions, much less engage in dialogue with the public has been well documented by many commenters over the years. However, the events that occurred during consideration of naphthalene at the November 2002 Subcommittee meeting warrant special mention.

The November 2002 RoC Subcommittee meeting exemplifies a case in which each of the basic principles of the Data Quality Act, objectivity, transparency and utility, seem to have been compromised. The Subcommittee Chair temporarily stepped down to join the discussion of naphthalene and participate in the vote. The Chair provided a document to Subcommittee members just prior to the break and suggested that the Subcommittee members review the Chair's comments during the break. The document was not made available to the public at the meeting or since. Following the break, seven minutes were allotted to the Panel to make a non-interactive oral presentation. At the conclusion of the public comment period, the Chair gave a highly technical presentation to the Subcommittee that included new information not previously shared with the Subcommittee nor made part of the public record. Members of the public present at the meeting were neither permitted to see the materials on which the presentation was based, nor ask questions, nor given additional time to make oral or written comments on the newly presented material.

The objectivity, transparency and utility of the process were compromised by the actions and processes NTP followed:

- The work of several well-regarded independent academic researchers, who have extensively published on the toxicology of naphthalene, was discussed in detail in the *Draft Background Document*. This widely accepted work on the metabolism of naphthalene was, however, dismissed as of little value. An alternative approach that has yet to be made public was proposed as relevant instead.
- The public was not permitted to see either the newly submitted document or the publications that were said to form the basis of the document at the Subcommittee meeting. No public comment was sought either at the Subcommittee meeting or since on either the criticisms of the published work and the presentation of that work in the *Draft Background Document* or on other issues raised during the Subcommittee's discussions as a result of the newly – and privately – introduced materials.
- Since the RoC Subcommittee meeting, NTP provided a list of three references to the Panel. These three published papers were purported to be the basis of the document

distributed to Subcommittee members at the meeting. The Panel has reviewed the literature cited and found that the papers are of little to no utility to the understanding of naphthalene carcinogenicity. In absence of further information, the Panel can only conclude that the presentation made by the Subcommittee Chair was personal opinion unsupported by published literature. The deference and acceptance of the privately distributed document by the RoC Subcommittee without a review of the underlying publications calls into question the scientific credibility of the RoC Subcommittee.

ROC LISTING/DELISTING DECISIONS SHOULD BE CLARIFIED.

If naphthalene is listed in the 11th RoC, it will be the first substance to be listed based on the following combination of scientific findings (1) "clear evidence" of carcinogenicity in one species of experimental animal (rat), (2) "some evidence" in one sex of a second species (mouse), and (3) that is not genotoxic. The scientific findings discussed extensively in the Panel's previously submitted comments clearly show that naphthalene should not be listed as "reasonably anticipated" to be a human carcinogen³. In addition to the questionable relevance of the rat results to humans, the basis for "some evidence" of carcinogenicity in female mice is one carcinoma in one of 135 female mice. This evidence is weak at best. Importantly, NTP should not use naphthalene or any other individual substance to affect a "change by precedent" in RoC listing evidence requirements. Any change to NTP's listing criteria should be submitted to other government agencies and the public for review and comment.

If you would like additional information, please call or e-mail Dr. Anne P. LeHuray at (703) 741-5630 or anne_lehuray@americanchemistry.com.

Sincerely yours,



Courtney M. Price
Vice President, CHEMSTAR

³ Supporting documents for the Panel's belief are contained in comments submitted to NTP dated March 24, 2003 (<http://ntp-server.niehs.nih.gov/newhomeroc/roc11naphthalene.html>).